K102915

510(k) Summary as required by section 807.92(c)

JAN 12 2011

Submitter's name: ViewRay Incorporated
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Contact person: Janice Brownlee

Date prepared: September 30, 2010

Trade Name of Device: ViewRay™ Treatment Planning and Delivery System

Common name: Radiation Therapy Treatment Planning and Delivery System

Classification name: Radionuclide Radiation System (21CFR 892.5750, Product Code IWB)

Predicate Device: Varian Medical Systems' Trilogy Mx™ System K092871 and Eclipse™ Treatment Planning System K091492

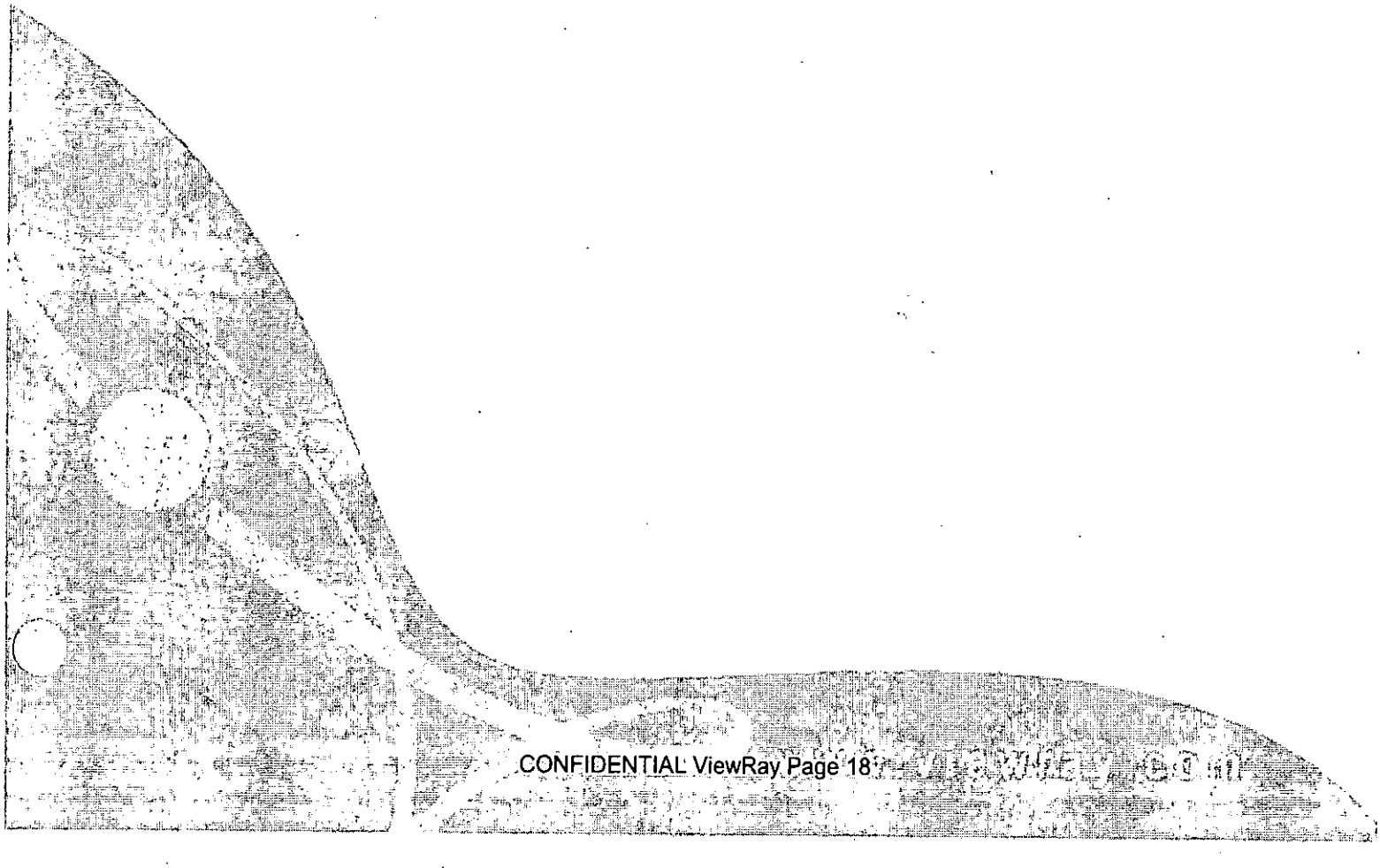
Description: The ViewRay™ Treatment Planning and Delivery System (TPDS) provides tools for planning and delivery of external gamma beam stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. It is a computer-based device used by trained medical professionals. The Treatment Planning software is only designed to be used on the ViewRay radiation therapy system. The ViewRay TPDS is capable of assisting clinicians in reviewing, prescribing, tracking, and correcting the course of patient treatment using tools for contouring, visualization, data storage, anatomical target monitoring and re-optimization.

The software described in this submission has been designed to conform with applicable sections of IEC 60601-1, IEC 60601-2-11, IEC 62083 and IEC 61217.

Intended use: The ViewRay™ Treatment Planning and Delivery System is intended to be used for planning external beam irradiation with photon beams and delivering stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated, in conjunction with the ViewRay™ System, an MRI image-guided radiation therapy system.

Technological Characteristics compared to predicate device: The ViewRay™Treatment Planning and Delivery System shares many of the technological features and characteristics of the Varian Eclipse planning system, and the treatment delivery features of the Varian Trilogy System. The fundamental technical characteristics are the same as those of the predicate devices and minor differences are described in the comparison chart and discussion provided elsewhere in this 510(k) submission.

Conclusion: The ViewRay™ Treatment Planning and Delivery System has the same intended use, indications for use and user population as the Varian Eclipse™/Trilogy Mx™ System. The ViewRay™ Treatment Planning and Delivery System has most of the features and technological characteristics as the predicate devices, and the few distinguishing characteristics do not raise new types of safety or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Janice Brownlee
VP, Regulatory Affairs and Quality Assurance
ViewRay Incorporated
2 ThermoFisher Way
OAKWOOD VILLAGE OH 44146

JAN 12 2011

Re: K102915
Trade/Device Name: ViewRay™ Treatment Planning and Delivery System
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: September 20, 2010
Received: November 1, 2010

Dear Ms. Brownlee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

1C. Regulatory Sections

Indications for Use JAN 12 2011

510(k) Number (if known): TBD K102915

Device Name: ViewRay™ Treatment Planning and Delivery System

Use of the ViewRay™ Treatment Planning and Delivery System is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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